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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.         | CONFIRMATION NO. |
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| 09/827,490      | 04/06/2001  | Elizabeth S. Stuart  | 08952-008001 / UMA<br>00-19 | 5744             |

7590 03/26/2002  
J. PETER FASSE  
Fish & Richardson P.C.  
225 Franklin Street  
Boston, MA 02110-2804

EXAMINER

FORD, VANESSA L

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1645

DATE MAILED: 03/26/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/827,490

Applicant(s)

STUART ET AL.

Examiner

Vanessa L. Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 January 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 1-6, 11-14 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-10, 15 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

1. Applicant's election of Group II, claims 7-10, 15 and 17, without traverse in Paper No. 6 is acknowledged. Claims 1-6, 11-14, and 16 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

#### ***Claim Objections***

2. Claim 7 recites "GLXA" which should be "chlamydial glycolipid exoantigen". The proper name for this term should be used at the first occurrence in the claims. Correction is required.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 7 and 9 are rejected under 35 U.S.C. 102(b) as anticipated Svenson et al (*Journal of Immunol Methods*, 1979, 25 (40:323-335).

Claims 7 and 9 are drawn to a composition comprising a carrier coupled to an oligosaccharide obtained from a chlamydial glycolipid.

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Svenson et al teach a composition comprising *Salmonella* specific oligosaccharides coupled to carriers using 2-(4-aminophenyl)ethylamine as the linker (see the Abstract).

Since the Office does not have the facilities for examining and comparing applicant's composition and purified exoantigen with the composition and purified exoantigen of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the composition and purified exoantigen of the prior art does not possess the same material structural and functional characteristics of the claimed composition and purified exoantigen). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

4. Claims 7 and 9 are rejected under 35 U.S.C. 102(b) as anticipated Kamath et al (*Glycoconj. Journal*, April 13, 1996, Volume 2, p. 315-319).

Claims 7 and 9 are drawn to a composition comprising a carrier protein coupled to oligosaccharide obtained from a chlamydial glycolipid.

Kamath et al teach a composition comprising carrier proteins coupled to oligosaccharide amines using diethyl squarate (see the Abstract).

Since the Office does not have the facilities for examining and comparing applicant's composition and purified exoantigen with the composition and purified exoantigen of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the

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composition and purified exoantigen of the prior art does not possess the same material structural and functional characteristics of the claimed composition and purified exoantigen). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

5. Claim 15 is rejected under 35 U.S.C. 102(b) as anticipated Stuart et al (*Immunology*, 1989, 68, p. 469-473).

Claim 15 is drawn to a purified chlamydial glycolipid exoantigen wherein the purified chlamydial glycolipid exoantigen that is free of other components as determined by sodium dodecylsulfate gel electrophoreses and silver staining.

Stuart et al teach purified chlamydial glycolipid exoantigen that is free of other components as determined by sodium dodecylsulfate gel electrophoreses and silver staining. The purified chlamydial glycolipid exoantigen of Stuart, et al appears to be the same as the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's exoantigen with the exoantigen of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the exoantigen of the prior art does not possess the same material structural and functional characteristics of the claimed exoantigen). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 7-10, 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacDonald et al (*Patent No. 5,716,793, published February 10, 1998*) in view of Semprevivo (*Carbohydrate Research, 1988, 177, p. 222-227*).

Claims 7-10, 15 and 17 are drawn to a composition comprising a carrier group coupled to an oligosaccharide obtained from the a chlamydial glycolipid.

MacDonald et al teach a chlamydial glycolipid exoantigen (GLXA) that is bound to labeled antibodies (i.e. Ab1 or Ab3) or a Fab fragment (column 8, lines 55-58 and column 9, lines 60-65). MacDonald teach a purified GLXA (column 13, lines 43-67 and column 34, lines 5-6). MacDonald et al polyclonal anti-chlamydial antibodies which were covalently bound to paramagnetic particles (column 14, lines 34-40).

MacDonald et al do not teach a 2-(4-aminophenyl)ethylamine linker.

Semprevivo teaches 2-(4-aminophenyl)ethylamine linkers. Semprevivo teach that oligosaccharides behave as simple haptens and must be linked either to proteins or a solid support in order to raise and isolate a specific antibody (see the Abstract).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use the 2-(4-aminophenyl)ethylamine linkers as

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taught by Semprevivo to conjugate the chlamydial glycolipid exoantigen (GLXA) to the labeled antibodies in the composition of MacDonald et al because Semprevivo demonstrates extremely consistent results that show that neoantigens produced by coupling derivatized oligosaccharides to protein react strongly with a preformed specific anti-oligosaccharide antibody (page 227). It would be expected barring evidence to the contrary that the use of 2-(4-aminophenyl)ethylamine linkers has broaden the applicability and conserved the chemical integrity of the oligosaccharide haptens (page 227).

#### **Status of Claims**

7. No claims are allowed.

#### **Pertinent Art**

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure (*MacDonald et al, Patent Number 5,840, 297, published November 24, 1998, MacDonald et al, Patent Number 5,656,271, published August 12 and MacDonald et al (Immunology and Host Parasite Interactions, in the Proceedings of the Euro. Soc. For Chlamydia Re., The Univ. of Bologna Press, Bologna, Italy, 140, 1988).*

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***Conclusion***

9. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.



Vanessa L. Ford  
Biotechnology Patent Examiner  
March 15, 2002



MARK NAVARRO  
PRIMARY EXAMINER